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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,441	06/26/2006	David L. Shelton	514712001600	5590

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/549,441	SHELTON, DAVID L.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-14 are under consideration.

2. The use of the trademark TAXOL has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

3. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8,13,14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed methods.

Claim 1 recites a method that uses an agonist antibody that binds trkC. According to the specification section [0042] the term "trkC" includes unknown variants and any trkC from any animal species. It appears that a specific human trkC was known in the art.

However, the claims encompass use of an antibody which binds a virtually unlimited collection of variants that are not known in the prior art or disclosed in the specification. Regarding claims that encompass antibodies that bind trkC other than human, it is unclear as to what species other than human or mouse trkC were known in the prior art. However, the claims encompass use of an antibody which binds trkC from any animal species. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claim 1 contains the trademark/trade name "taxol". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe taxol and, accordingly, the identification/description is indefinite.

8. Regarding priority for the claimed invention and the application of prior art, the invention of claims 9-12 is not disclosed in parent application 60/456648, therefore said inventions are not entitled to priority to said application.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-8,13 are rejected under 35 U.S.C. 102(b) as being anticipated by Devaux et al. (WO 01/98361).

Devaux et al. teach the claimed pharmaceutical composition containing an agonist anti-trkC antibody (see claim 49). The recitation of an intended use carries no patentable weight in the aforementioned claimed product. The specification, section [0046] discloses that "treatment" encompasses "preventing occurrence" of a taxol induced disorder. In order to prevent occurrence of the taxol induced gut disorder, the antibody would have to be administered before the disorder occurred (aka during initial administration of taxol, but before the disorder occurred, e.g. as per the Example in the specification). Thus, the claims encompass treatment of an individual who has received taxol but does not yet have a taxol induced gut disorder. Devaux et al. teach use of the antibody recited in the claims to treat peripheral neuropathy (see claims 50,51,1-6) wherein one such peripheral neuropathy is taxol induced (see page 12, last paragraph, continued on next page). Devaux et al. teach that "treatment" encompasses prevention of the disease (see page 12, first complete paragraph). Devaux et al. also teach that the antibody can be administered at the same time as the administration of the disease provoking agent (see page 54, third and fourth paragraphs). Thus, prevention of taxol induced neuropathy would achieved by treating a patient receiving taxol before the disease occurred (during initial administration of taxol). Therefore, both the claimed invention and the teachings of Devaux et al. encompass administration of the same antibody to patients which are receiving taxol and do not yet have disease wherein the antibody would be administered at the time that the taxol was administered.

11. Claims 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Pons (WO 2005/062955).

The claims encompass treatment of a taxol receiving patient before onset of disease for the reasons elaborated above. Pons teaches the antibody containing the sequences recited in the claims (see pages 74-77) and that it can be administered before the neuropathy inducing agent (see [0236]). Pons discloses that said antibody can be adminstered before the TAXOL induced neuropathy occurs (aka before or during TAXOL administartion, see [0183], [0200]).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-8,13,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devaux et al. (WO 01/98361) in view of Ashkenazi et al. (US 6,252,050).

Devaux et al. teach the claimed pharmaceutical composition containing an agonist anti-trkC antibody (see claim 49). The recitation of an intended use carries no patentable weight in the aforementioned claimed product. The specification, section [0046] discloses that "treatment" encompasses "preventing occurrence" of a taxol induced disorder. In order to prevent occurrence of the taxol induced gut disorder, the antibody would have to be administered before the disorder occurred (aka during initial administration of taxol, but before the disorder occurred, e.g. as per the Example in the specification). Thus, the claims encompass treatment of an individual who has received taxol but does not yet have a taxol induced gut disorder. Devaux et al. teach use of the antibody recited in the claims to treat peripheral neuropathy (see claims 50,51) wherein one such peripheral neuropathy is taxol induced (see page 12, last paragraph, continued on next page). Devaux et al. teach that "treatment" encompasses prevention of the disease (see page 12, first complete paragraph). Devaux et al. also teach that the antibody can be administered at the same time as the administration of the disease provoking agent (see page 54, third and fourth paragraphs). Thus, prevention of taxol

induced neuropathy would achieved by treating a patient receiving taxol before the disease occurred (during initial administration of taxol). Therefore, both the claimed invention and the teachings of Devaux et al. encompass administration of the same antibody to patients which are receiving taxol and do not yet have disease wherein the antibody would be administered at the time that the taxol was administered. Devaux et al. do not teach the claimed kit.

Ashkenazi et al. teach kits containing a therapeutic antibody and instructions (see column 26). The recitation of an intended use carries no patentable weight in the instant kit claims. The instructions for use carry no patentable weight in the instant kit claims (see In Re Ngai (70 USPQ 2D 1862) CAFC). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Devaux et al. teach the claimed therapeutic antibody and Ashkenazi et al. teach kits containing a therapeutic antibody and instructions. One of ordinary skill in the art would have been motivated to do the aforementioned for convenience of use.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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